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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,223	04/08/2004	G.R. Barrie Webster	84676-302	7119
23529	7590	12/09/2005	EXAMINER	
ADE & COMPANY 1700-360 MAIN STREET WINNIPEG, MB R3C3Z3 CANADA			SPIVACK, PHYLLIS G	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 12/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/820,223	WEBSTER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

The undersigned Examiner supports the goal of the Office to advance prosecution as expediently as is reasonably possible. Co-operation is requested with respect to the timely submission of any references deemed pertinent to the present application along with Form PTO-1449.

Claims 1-8 are presented and represent all of the claims under consideration.

The disclosure is objected to for the following informality: In the Abstract "is" should be -- are.

On page 2, line 17, of the specification "potentiate" is misspelled.

Appropriate correction is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Mueller, A., US 2004/0049059.

Mueller teaches a pharmaceutical composition in the form of an extract comprising 1 part cannabidiol to 2 parts  $\Delta^8$ -tetrahydrocannabinol (No. 5) which may be employed as an antiemetic in pediatric oncology. See page 3, [0037], line 6, page 4, [0063], and Table 4, page 8. The open language of the present claims allows for the inclusion of any number of additional active ingredients.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1614

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abrahamov et al., Life Sciences, in view of Karniol and Carlini, Psychopharmacologia, Karniol et al., Eur. J. Pharma., Zuardi et al., Psychopharmacology, and Hollister and Gillespie, Clin. Pharmacol. Ther.

Abrahamov teaches the administration of  $\Delta^8$ -tetrahydrocannabinol ( $\Delta^8$ -THC) to treat the nausea and vomiting that occurs following cancer chemotherapy in a pediatric population. Various dosage regimens were employed; however, most patients received a dose of 18 mg/m<sup>2</sup> or 20 and 40 mg total dose. Abrahamov fails to include administration of cannabidiol (CBD). However, motivation is provided through the teachings of Karniol, Zuardi and Hollister to include CBD in combination with  $\Delta^8$ -THC. It would have been obvious in the absence of evidence to the contrary to administer a pharmaceutical composition comprising both  $\Delta^8$ -THC and CBD because CBD blocks the excitatory effects of  $\Delta^9$ -THC. CBD attenuates side effects of  $\Delta^9$ -THC, such as pulse rate acceleration, time production impairment and psychological disturbances. CBD decreases the anxiety effect associated with  $\Delta^9$ -THC. CBD retards and prolongs the duration of effect of  $\Delta^9$ -THC.  $\Delta^8$ -THC is a double bond isomer of  $\Delta^9$ -THC and is a cannabinoid with lower psychotropic potency than  $\Delta^9$ -THC. The determination of an optimal ratio of the active agents, as well as optimal dosages, are parameters well within the purview of those skilled in the oncology art through no more than routine experimentation.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 4, 2005



Phyllis Spivack

1614

**PHYLLIS SPIVACK  
PRIMARY EXAMINER**